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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,505	10/17/2003	Bnan Broussard	DB001056-001	1986
24122	7590	08/09/2005	EXAMINER	
THORP REED & ARMSTRONG, LLP ONE OXFORD CENTRE 301 GRANT STREET, 14TH FLOOR PITTSBURGH, PA 15219-1425			LE, THIEN MINH	
			ART UNIT	PAPER NUMBER
			2876	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/688,505		BROUSSARD ET AL.	
	Examiner		Art Unit	
	Thien M. Le		2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 30-42 is/are rejected.
- 7) ☒ Claim(s) 29 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on 4/18/2005 has been entered. The information disclosure statement filed on 2/18/2005 has been entered. Claims 1-43 remain for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-28 and 30-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Liff et al. (Liff et al. – 2005/0065645 A1; herein after referred to as Liff; newly cited).

Regarding claims 1, 4, 16, 30, Liff discloses “an automated drug dispensing system includes a cabinet adapted to store a variety of prepackaged pharmaceuticals in a plurality of bins for filling patient prescriptions. Each bin stores a particular variety of packaged multiple-dose pharmaceutical. Each variety of pharmaceutical is associated with a particular code. A controller receives request signals and in response generates dispense signals. Each bin includes a dispenser coupled to the controller for dispensing the packaged pharmaceuticals therefrom in response to a dispense signal sent from the controller. After a package is dispensed, a code reader determines the code of the dispensed package and verifies whether the code on the dispensed package matches the code of the requested package.” (see the abstract)

Specifically, Liff discloses in paragraph [0053] that “a licensed user, for example, a doctor, pharmacist, nurse, or other medical practitioner qualified to fill patient prescriptions, operates the system at the host computer 46, using a keyboard 50 and mouse 66 for input and receiving visual feedback at a monitor 48. Using the keyboard 50, a user enters a command to request dispensing of a particular packaged pharmaceutical variety 32 for a particular patient. The computer 46 transmits the request via an interface 70 to a controller 42 located on the RCD cabinet 20. The controller 42 interprets the command sent from the computer 46 and enables a dispensing actuator 68 in the appropriate column 34. The lowest package 32 in the appropriate column 34 is released from the column 34 and ejected onto a ramp 30. The released package 74

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slides down the ramp 30 into an opening 26, where the released package 74 is made available to the dispensing party for transfer to the patient.”

According one it has been determined that the “drug is stocked at the RCD unit, then patient data is retrieved 275, the drug is selected 276, the prescription signa is selected 277 and additional scripts may be entered 278. Following this, the identification number of the prescriber is entered 279 and all data is transmitted to the R.H. workstation 280. At the R.H. workstation, the pharmacist verifies the prescription 281 and performs a drug utilization review 282. If issues arise during the review, the pharmacist is immediately made aware of the conflict and given an opportunity to review and, if appropriate, override 283 the interventions 284. If the pharmacist decides at this point to discontinue the dispensing 285, the process is aborted 294. If the pharmacist decides to continue the dispensing anyway 284 or there were no interventions 283 in the first place, then claim adjudication is performed 286. During adjudication 286, a patient's insurance information is automatically verified to determine whether the insurer will pay for the prescription, and if so, if any co-payment is required from the patient. If a negative response is received 287, drug dispensing is aborted 291. Otherwise, the drug is dispensed and verified with a bar code reader 288. If an improper drug was dispensed, the technician is notified to abort the process as a system failure has occurred 292. Upon system failure electronic notification is performed. Distribution headquarters or a regional dispensing location or agent can be notified by the RCD system of an incorrect dispense is shown. Electronic notification can take the form of a fax, email, file transfer, pager notification, or any other electronic transfer protocol. If verification is positive, a label is

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printed and affixed to the bottle 290, and the prescription is dispensed to the patient by the technician 293.”

Liffer further discloses that “Upon entering the operating system 303, the program starts 306 at a main menu 307. The main menu 307 is referred to as a jump screen shown in FIG. 14A. At the jump screen 500, the operator can select from several options including: entering a new prescription 308, refilling a prescription 310, entering new patient information 311, generating reports 312, performing maintenance functions 315, or exiting the system 313. Each selection requires the operator to enter a password 309A-309E. The password function 309A-309E provides an appropriate level of security for each task. For example, generating a new prescription 308 may require a high level of security, for example, the pharmacist, while generating a report 312, may require a lower level of security, for example, a technician.” (see paragraph [0123])

Liff discloses in paragraph [0127] that in “the drug window 323C, shown in FIG. 14D, the operator is prompted to select from a pop-down menu 505 of drugs available in the RCD units. When a drug is selected, the generic name, brand name, and NDC number of the drug available in the RCD unit automatically appears in the window, along with the quantity of doses in each bottle. At this time, the operator is afforded an opportunity to select a generic substitution 506, as opposed to a brand name drug. A generic substitution generally saves money for the patient and tends to be a more current formula for the drug. Label data to be printed upon dispensing is automatically updated by the software to include the generic drug information. In addition, the software automatically maintains an inventory and keeps track of the drugs which have been dispensed and assures a first-in-first-out inventory process. This

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provides a round-robin dispensing system so that drugs are continually circulated and therefore, expiration dates will pass less frequently. In addition, this system averages out solenoid use for each column in the cabinet such that one column does not wear more quickly than other columns in the cabinet. The drug window 323C also requires the operator to select an ICD-9 disease code from a pop-down menu 507. The ICD-9 code is an industry standard code number for a variety of ailments known to physicians.”

Liffer further discloses the steps of review generic drug choice base on patent's medical history, rules, as shown in figures 14E, 14F, 14G, 14H, the regulations from NDC, etc.

As can be seen, Liff discloses various method of receiving prescription data (figures 7-14), the step of generating list of generic drug and selecting a particular drug (figures 7-14, the discussions and description regarding figures 14E-14H), and the step of automatically printing the generic drug information; and thus would embrace all limitations set forth in this claim.

Regarding claim 2, see the discussions regarding claim 1.

Regarding claim 3, the generic drug is selected by the customer, the operator, the pharmacist, the drug trial results, the regulations, etc., as has been discussed above; and would embrace all limitations set forth in this claim.

Regarding claims 5-6, see the discussions regarding claims 1-4, figures 7-14 of Liff and their descriptions.

Regarding claim 7, Liff discloses in the summary of the invention that “the present invention combines computer hardware and software, a telecommunications capability, and a

medication container dispensing cabinet to form a complete in-office dispensing system. This enables drug prescription dispensing in volume by a physician, pharmacist, or other licensed practitioner directly to the patient at a clinic, group practice, or other location outside a pharmacy or hospital. The system provides a convenient, safe, automated, and low cost drug delivery system for the patient”; and that would embrace all limitations set forth in this claim.

Regarding claims 8 and 32, Liff discloses that “FIG. 32 is an illustration of an alternative dispensing unit. The unit includes a plurality of workstations 678, each workstation having a corresponding dispensing port 680. The unit further includes a cabinet 682 for storing a variety of pharmaceuticals and a conveyer means 684 for conveying a dispensed pharmaceutical from the cabinet area 682 and for distributing it to the appropriate dispensing port 680. Each workstation 678 also includes a printer for printing labels and instructions as described herein and a bar code reader for verifying that proper dispensing has occurred;” and thus would embrace all limitations set forth in this claim.

Regarding claims 9, 19, 33, in paragraph 0084, Liff discloses the method of indicating that dispensing operation is completed so that a customer can pickup the order. Since Liff’s system also allowed filling with generic drug, the examiner considered that the step of indicating/alerting the completion of a dispensing operation would happen in the same manner for the case of dispensing a generic drug.

Regarding claims 10, 20, 34, see the discussions regarding claims 1-8. Also see figure 13K where transaction is recorded in database 407. Further, various patent/drug

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dispensing records are maintained and described through out the specification of the Liff reference.

Regarding claims 11, 15, 18, 21, 25, 35, 39, when the prescription filling is improper, a warning will be generated to inform the operator, the pharmacist, head quarter, etc., (paragraph 0088). Since Liff also discloses the method of generating and choosing a generic drug, the examiner is of the view that if the prescription dispensing is not proper with a generic drug, a warning is also generated by Liff's system.

Regarding claim 12, see the discussions above regarding claim 1.

Regarding claims 13, 17, 23, 31, regarding the method of updating inventory control, see the discussions and descriptions of figure 2 of Liff.

Regarding claims 14, 22, 24, 37-38, see the discussions for the printing steps as discussed in claim 1.

Regarding claims 26-28, 40-42, see the discussions above regarding claims 1-25.

Remarks

Applicant's arguments filed on 4/18/2005 have been considered but are mood in light of the new grounds of rejection.

Allowable Subject Matter

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Claims 29 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art disclose various method of filling prescriptions including the steps of reviewing and selecting generic drug, printing and providing information. However, the prior art fail to disclose the combined step of manually filling a prescription comprising the steps of receiving prescription data; automatically applying substitution rules; retrieving a stock bottle; dispensing the bottle; creating substitution reference list; and especially the step of generating a warning when the substitution reference lists are not available.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thien M. Le whose telephone number is (571) 272-2396. The examiner can normally be reached on Monday - Friday from 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Le, Thien Minh
Primary Examiner
Art Unit 2876
August 2, 2005